

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/US2004/017340	International filing date (day/month/year) 03.06.2004	Priority date (day/month/year) 03.06.2003	
International Patent Classification (IPC) or national classification and IPC G01N21/27			
Applicant BAYER HEALTHCARE, LLC			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 9 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  04.04.2005		Date of completion of this report  02.06.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer D'Alessandro, D Telephone No. +31 70 340-1919 	

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-17 as originally filed

**Claims, Numbers**

1-22 as originally filed

**Drawings, Sheets**

1/8-8/8 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 4,10,16

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4,10,16 are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-3,5-9,11-15,17-18,21,22
	No: Claims	19,20
Inventive step (IS)	Yes: Claims	
	No: Claims	1-3,5-9,11-15,17-22
Industrial applicability (IA)	Yes: Claims	1-3,5-9,11-15,17-22
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The subject-matter of claims 4, 10, 16 refers to the determination of the high resolution reflectance values  $\{r\}$ . The definition given in these claims and in the description (par. 13, par. 46) suggests that the individual elements  $r_i$  of vector  $\{r\}$  depend respectively on the measured reflectance values  $R$  of claim 1, at the same wavelength. This definition implies that the number of elements of vector  $\{r\}$  is equal or less to the number of values  $R$  available.

2. On the contrary, it appears from eqs. (3), (5) of the description, that each reflectance value  $R$  can be written as an expression involving the sum of the vector  $\{r\}$  over its index. From this part of description, the skilled person understands that:

- the elements  $r_i$  of vector  $\{r\}$  are defined at the same set of reference wavelengths as vectors  $\{L\}$ ,  $\{L^*\}$ ,  $\{D\}$ , at a wavelength step of less than 1 nm (see par. 51);
- the vector  $\{r\}$  represents the reflectance spectrum of a target chemical at the reference wavelengths, which is known *a priori* (see also par. 64, fig. 7A) with good resolution;
- for each light source (6 for the embodiment disclosed), there is one overall reflectance value  $R$ , that is expressed in terms of the sum of all the elements of vector  $\{r\}$ .

This contradicts the assumption made in point 1, that the the number of elements of  $\{r\}$  is the same or less than the number of values  $R$ . A possible cause of this contradiction is that the meaning of symbol  $R$  in claim 4 is not the same as in claim 1.

3. Due to this inconsistency, the mentioned claims are unclear (Art. 6 PCT), and no opinion on them has been established. For the examination of the independent claims, the definition of vector  $\{r\}$  has been interpreted as set forth in point 2 above.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO 02/14793 A (DIETIKER THOMAS ; ELEKON IND INC (US)) 21 February  
2002 (2002-02-21)

D2: EP-A-0 816 829 (HUTCHINSON TECHNOLOGY) 7 January 1998 (1998-01-07)

The present application does not meet the criteria of Article 33(1) PCT, because

the subject-matter of claims 19,20 is not new in the sense of Article 33(2) PCT, and

the subject-matter of claims 1-3,5-9,11-15,17-18,21-22 does not involve an inventive  
step in the sense of Article 33(3) PCT.

1.1 The document D1 is regarded as being the closest prior art to the subject-matter of  
claim 1, and discloses (the references applying to this document):

<i>p. 2, last par.;</i> <i>p. 6, par. 1</i>	A method of correcting one or more reflectance values when a center wavelength of one or more light sources used to generate corresponding light signals is different from a specified center wavelength for the one or more light sources, comprising:
<i>p. 7, par. 4;</i> <i>p. 10, par. 3</i>	defining, for each of the one or more light sources, the center wavelength;
<i>p. 7, par. 2;</i>	determining the actual reflectance for the incident light;
<i>p. 7, par. 4;</i>	determining a correction factor, which is dependent on the center wavelength, in order to compensate the center wavelength error.

The use of the reference spectrum {r} of the target chemical (oxygen in D1 *p. 6, par. 1*), as  
well as detector sensitivity data for the calculation of the correction factor, is considered

implicitly disclosed in D1.

Although the method of D1 refers to the calibration of an instrument by measuring the center wavelength of a light source prior to introducing a sample in the instrument, this does not mark any difference with the subject-matter of claim 1. Also in claim 1 actually, the characteristics of the light sources (vector {L}) are determined regardless of the sample under test. Because every calibration method implies the calculation of a correction factor to correct the measured values during the use of the instrument, there is furthermore no difference between a "calibration" method and a "correction" method.

In the light of the disclosures of D1, the actual difference between the subject-matter of claim 1 and the known method, is the calculation of the correction factor taking into account the power spectral density of the source at a set of wavelengths, rather than just the centroid of the spectrum as in D1. This step allows to compensate the spectral variations with a greater accuracy, in particular when more than one source is used to measure the reflectivity of the sample. Document D2 discloses a method for measuring the absorption spectrum of a sample using light from a plurality of sources (*p. 9, l. 37-44*), in which a spectrum of the incident light is recorded prior to measurement (*p. 7, l. 6-8*). To reach the required detail in the calculation of the correction factor, the person skilled in the art would include this step in the method of D1, obtaining as a consequence the subject-matter of claim 1. The subject-matter of claim 1 does not therefore involve an inventive step (Article 33(3) PCT).

1.2 The subject-matter of independent claims 7,13 is an apparatus whose technical features perform the steps of the method of claim 1. Therefore, the same reasoning as for claim 1 applies, and these claims are considered not inventive.

The applicant should take into account that is not clear neither from the description nor from the claims whether the spectral distribution module (feature A) belongs to the reflectometer or it is an external device.

1.3 For the same reasons as in 1.2, also the subject-matter of claim 21 is considered not inventive.

1.4 The additional feature:

the correction factor can be determined for variations of the center wavelength larger

than  $\pm 8$  nm from the nominal wavelength (cls. 2,8,14)

is implicitly disclosed in D1, given the dynamic range of the wavelength sensor (see *fig. 9*) and the considerations at *p. 6, par. 1*. Document D1 also discloses:

<i>p. 7, par. 2;</i>	the one or more light sources comprise LEDS (cls.
<i>fig. 4B</i>	3,9,15,22);
	the light sources and detectors are part of a
	reflectometer (cls. 6,12,18);

Furthermore, determining the values of  $\{r\}$  at discrete wavelengths intervals (cls. 5,11,17) is the necessary step taken when storing spectra in a memory.

In conclusion, the subject-matter of the mentioned claims does not involve an inventive step.

2. Document D2 discloses the following features of independent claim 19:

<i>fig. 15</i>	A reflectometer, comprising:
<i>p. 9, l. 37-44</i>	a set of light sources;
<i>p. 10, l. 5-12</i>	a set of detectors;
<i>p. 7, l. 20-24</i>	a reflectance assembly configured to direct light signals from the sources onto a sample and reflected light from a sample to the detectors;
<i>p. 13, l. 18-23</i>	a storage device;
<i>p. 14, l. 18-20;</i>	a processor
<i>p. 14, l. 46-52</i>	

Although the sample in D2 is human skin, no modifications of the disclosed apparatus are required in order to analyze test products as in claim 19. The storage device of claim 19 is defined in terms of the data it is able to store, while the correction function module is defined by the operation it performs rather than by its technical features. Because conventional memory units and processors would be suitable for the same purposes, these definitions are not considered as limiting the subject-matter of the claim. Therefore, in the light of the cited disclosures of D2, claim 19 is not new. The same reasoning applies



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(SEPARATE SHEET)**

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to dependent claim 20.

2.1 Were feature E of claim 19 be interpreted as "a correction function module configured to determine a correction factor...", as in claim 7, the subject-matter of this claim would not anyway be proven inventive, for the same reasons set forth for claims 1,7,13.